

REMARKS

FORMAL MATTERS:

Claims 1, 3, 6, 8-16, 18, 21 and 23-34 are pending in the application after entry of the amendments set forth herein.

Claims 7 and 22 have been cancelled without prejudice. Claims 2, 4-5, 17 and 19-20 remain cancelled.

Claims 1, 16, and 31 have been amended. Support for these amendments is found in the claims as originally filed, e.g., Claim 7 and 22 and throughout the specification, e.g., at page 15, line 32 – page 16, line 11.

No new matter has been added.

REJECTIONS UNDER 35 U.S.C. § 112 FIRST PARAGRAPH

Claims 1, 3, 6-16, 18, and 21-34 are rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement.

In making this rejection, the Examiner asserts that the instant application claims subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner asserts that Claims 1, 3, 6-16, 18, and 21-34 do not comply with the written description requirement because the claims “require the component providing the hydrophilic domains be ‘non-reactive’” and that the claims allegedly do not “appear to have any support for a limitation excluding the use of reactive components for these domains”.

In the spirit of expediting prosecution and without conceding to the correctness of the rejection, Claims 1, 16 and 31 have been amended to remove the element of “a non-reactive component”. As such, the Applicants respectfully submit that the amended claims sufficiently comply with the written description requirement.

Accordingly, in view of the amendments to the claims and the remarks made above, the Applicants respectfully request that the rejection of Claims 1, 3, 6-16, 18, and 21-34 under 35 U.S.C. § 112, first paragraph, be withdrawn.

REJECTIONS UNDER 35 U.S.C. § 112 SECOND PARAGRAPH

Claims 1, 3, 6-16, 18, and 21-34 are rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In making this rejection, the Examiner asserts that “[b]ecause there is no support for the hydrophilic domains being ‘non-reactive’ as discussed above, it is entirely unclear what the scope of this new limitation is”.

As noted above, Claims 1, 16 and 31 have been amended to remove the element of “a non-reactive component”. As such, the Applicants respectfully submit that the limitations of the amended claims are sufficiently clear and are therefore, not indefinite.

Accordingly, in view of the amendments to the claims and the remarks made above, the Applicants respectfully request that the rejection of Claims 1, 3, 6-16, 18, and 21-34 under 35 U.S.C. §112, second paragraph, be withdrawn.

REJECTIONS UNDER 35 U.S.C. § 103(A)

Claims 1, 3, 6-11, 29, 31, 32, and 34-Say, Mizutani, Saby

Claims 1, 3, 6-11, 29, 31, 32, and 34 were rejected under 35 U.S.C. §103(a) as being unpatentable over Say et al. (US Patent No. 6,103,033) in view of Mizutani et al. (Bull. Chem. Soc. Jpn., 64, 1991, pp. 2849-2851) and/or Saby et al. (Analytica Chimica Acta, 304, 1995, pp 33-39).

In making the rejection, the Examiner asserts that Say teaches all of the claimed limitations apart from the element of “a polymer that provides hydrophilic domains in the conductive ink”. (Office Action mailed October 9, 2009 at page 4) To remedy this deficiency, the Examiner cites Mizutani for allegedly teaching “combining the enzyme with a polymer such as polyethylene glycol (PEG) to improve the activity of the enzyme” and Saby for teaching that “PEG prevents the enzyme from denaturing in the carbon electrode”.

In order to meet its burden in establishing a rejection under 35 U.S.C. § 103(a), the Office must first demonstrate that the combined prior art references teach or suggest all the claimed limitations. *See Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007)

(“the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make [every element of] the composition or device, or carry out the [entire] claimed process, and would have had a reasonable expectation of success in doing so,” (citing *KSR Int’l Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1395 (U.S. 2007))).

In the spirit of expediting prosecution and without conceding to the correctness of the rejection, Claims 1, 16 and 31 have been amended to specify that the “spacing between the working electrode and the second electrode does not exceed 200 micrometers”. As such, the spatial dimensions of the arrangement of electrodes are such that the space between the working electrode formed by the conductive ink and the second electrode is not larger than 200 micrometers.

The Examiner asserts that Say teaches this element and has cited column 11, lines 22-36 to support this assertion (Office Action mailed October 9, 2009 at page 5) and further states that “it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of either Mizutani and/or Saby for the biosensor of Say so as to improve the activity of the enzyme in the conductive ink by allowing it to better dissolve into or to prevent it from denaturing in the carbon based ink of Say”.

However, the Applicants respectfully disagree and submit that in asserting that the combination of Say and Mizutani and/or Saby teaches every element of the claimed invention, including the spatial dimensions of the electrodes, the Examiner has not considered the teachings of Say and Mizutani/Saby in their entirety.

According to MPEP §2143.03, “[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F. 2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert denied, 469 U.S. 851 (1984).” Furthermore, MPEP §2146 states that “[i]t is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F. 2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983).”

Contrary to the assertions of the Examiner, the Applicants submit that one of ordinary skill in the art, absent the instant disclosure, could not combine the teachings of Say with

Mizutani and/or Saby to arrive at the claimed invention when Mizutani and/or Saby are considered in their entirety.

To the contrary, incorporation of the hydrophilic polymer into the conductive ink of the electrode goes beyond mere combination of the elements as they appear in the prior art. Say does not teach incorporating a hydrophilic polymer in the conductive ink. Mizutani and Saby teach incorporating a PEG-modified enzyme in the conductive ink to produce electrodes which have dimensions of 3 mm or larger. (See e.g., Mizutani at page 2849, right column, second full paragraph which states “a portion of the mixture was placed in a hole (3.2 mm diameter, 4 mm deep) at the end of the electrode body”). Therefore, in contrast to the electrode arrangements as claimed, the combination of Say with Mizutani and/or Saby in the manner asserted by the Examiner would be expected to produce an electrode arrangement having large spatial dimensions such as those disclosed by Mizutani and Saby.

Therefore, the Applicants submit that the Examiner has improperly used hindsight reconstruction to combine the teachings of Say with Mizutani and/or Saby to arrive at the presently claimed invention. In considering the teachings of Say, Mizutani and Saby, there is no objective reason to believe that an electrode arrangement having the claimed spatial dimensions would be possible when a hydrophilic polymer has been incorporated into the conductive ink. Indeed, Say is completely silent to a hydrophilic polymer in the conductive ink and both Mizutani and Saby teach preparing large (e.g., greater than 3mm) electrodes when incorporating a PEG-modified enzyme in the conductive ink.

Therefore, Applicants contend that the Examiner has not established that the claimed invention as a whole would have been obvious to a person of ordinary skill in the art when considering the combination of prior art references in their entirety. As such, the Applicants submit that a *prima facie* case of obviousness has not been established, and thus respectfully request withdrawal of this rejection.

Claims 1, 3, 6-11, 29, and 31-Say and Charlton

Claims 1, 3, 6-11, 29, and 31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Say et al. (US Patent No. 6,103,033) in view of Charlton et al. (US Patent No.

5,798,031). This rejection is reiterated from previous Office Actions mailed October 2, 2008 and February 2, 2009.

In making this rejection, the Examiner asserts that Say teaches all of the claimed limitations apart from the element of “a polymer that provides hydrophilic domains in the conductive ink”. (Office Action mailed October 9, 2009 at page 4) To remedy this deficiency, the Examiner cites Charlton for its alleged teaching that “the enzyme can be deposited down onto an electrode in presence of a hydrophilic polymer, which would increase hydration access to the enzyme itself.”

It is the Applicant's position (as discussed in detail in the Response to Office Action dated August 19, 2008 and in the Appeal Brief dated November 7, 2008) that Charlton does not teach incorporation of the hydrophilic polymer in the conductive ink of the working electrode. As such, the combination of Say and Charlton does not teach each and every element found in the claims as required to establish a *prima facie* case of obviousness. For the sake of brevity, the Applicants' prior arguments are not reiterated herein.

However, in maintaining this rejection, the Examiner stated:

50. With respect to applicant's arguments concerning the continued use of Charlton in the rejections above, applicant repeatedly refers to and relies on information contained with Appendix A of Skoog et al, which applicant states was being provided. However, applicant does not appear to have provided said teaching and the examiner cannot appropriately respond to any of these arguments relying on Skoog when such teaching that has not been presented to the examiner.

Applicants apologize for any confusion the above error may have caused and enclose the Skoog reference (Exhibit 1) with this response. Applicants respectfully address the Examiner's comments below. Specifically, the Examiner stated in the Office Action dated February 2, 2009 that:

20, ll. 10-29. Because Say recognized that a number of non-conductive agents can be added to a conductive ink without destroying its sensing properties, one possessing ordinary skill in the art would recognize that adding any additional non-conductive agent, which the examiner would note applicant only adds in a 1% amount in the present invention (p. 20, ll. 25-27), would not destroy the function of the electrode. Moreover, the examiner is confused by the argument that one possessing ordinary skill in the art would not anticipate that incorporating a hydrophilic polymer into a conductive ink would allow the hydrophilic polymer to maintain its properties while also allowing the conductive ink to maintain its properties. A hydrophilic polymer is

The Applicants respectfully disagree with the assertions of the Examiner. Addition of electrically conductive components to an electrode will affect the function of the electrode. As stated in Skoog et al. (Exhibit 1), "it is useful to think of the cell reaction of an electrochemical cell as being made up of two half-cell reactions, each of which has a characteristic electrode potential associated with it." The electrode potential depends, in part, on the substance used to make the electrode. Table 19-1 of Skoog et al. summarizes a few electrode potentials. The table illustrates that different materials have different electrode potentials. Thus, if this concept is understood, one of ordinary skill in the art would not be motivated to incorporate additional elements in the conductive ink as different substances in the ink could affect the electrode potential in different ways.

The Examiner states that Say recognizes that a number of non-conductive agents can be added to a conductive ink without destroying its sensing properties. However, a hydrophilic polymer can be a conductive agent. As a result, addition of a hydrophilic polymer to a conductive material can affect the electrode potential of the conductive material (see for example Skoog et. al.). As such, there is no objective reason to believe that, absent the instant disclosure, an electrode produced incorporating additional chemical compositions (i.e., hydrophilic polymer) in the conductive ink could function properly. For this reason alone, the Examiner has failed to establish a *prima facie* case of obviousness.

Furthermore, in the spirit of expediting prosecution and without conceding to the correctness of the rejection, Claims 1, 16 and 31 have been amended to specify that the "spacing

between the working electrode and the second electrode does not exceed 200 micrometers”. As such, the spatial dimensions of the arrangement of electrodes are such that the space between the working electrode formed by the conductive ink and the second electrode is not larger than 200 micrometers.

As discussed in detail above, the Applicants submit that absent the instant disclosure as a guide, there is no objective reason to believe that an electrode arrangement where “spacing between the working electrode and the second electrode does not exceed 200 micrometers” as required by the instant claims, would be possible after incorporating a hydrophilic polymer in the conductive ink. As evidenced by the large spatial dimensions of electrodes when a PEG-modified enzyme is incorporated into the conductive ink (see above discussion above regarding Mizutani and Saby), the incorporation of a hydrophilic polymer into the conductive ink of the electrode goes beyond mere combination of elements as they appear in the prior art. Indeed, nowhere in Say and Charlton is it disclosed that a hydrophilic polymer is incorporated into the conduct ink, much less incorporating a hydrophilic polymer in the conductive ink and producing an electrode arrangement with the claimed spatial dimensions.

Therefore, Applicants contend that the Examiner has not established that the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time of the invention. As such, the Applicants submit that a *prima facie* case of obviousness has not been established, and thus respectfully request withdrawal of this rejection.

Claims 1, 3, 6-16, 18, and 21-34-Feldman, Say, Mizutani, and Saby

Claims 1, 3, 6-16, 18, and 21-34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Feldman in view of Say and either Mizutani and/or Saby.

As stated above, when considering the entirety of their disclosures, the combination of Say, Mizutani, and Saby, fails to teach or suggest an arrangement of electrodes prepared by incorporating a hydrophilic polymer in the conductive ink such that “spacing between the working electrode and the second electrode does not exceed 200 micrometers” as claimed.

Feldman does not teach or suggest preparing an electrode by incorporating a hydrophilic polymer in the conductive ink. Thus, Feldman can not remedy the deficiencies of Say, Mizutani,

and Saby nor remedy the deficiencies in the combination of the references when considered in their entirety.

Applicants thus, respectfully request withdrawal of this rejection.

Claims 1, 3, 6-16, 18, and 21-31-Feldman, Say, and Charlton

Claims 1, 3, 6-16, 18, and 21-31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Feldman in view of Say and Charlton.

As noted above, the combination of Say and Charlton fails to teach each and every element of the claimed invention. Specifically, neither Say, nor Charlton **teach incorporation of a hydrophilic polymer in the conductive ink of the working electrode**. Furthermore, there is no objective reason to believe that, absent the instant disclosure, an electrode produced by incorporation of hydrophilic polymer in the conductive ink could function properly.

As Feldman is completely silent to preparing an electrode by incorporating a hydrophilic polymer in the conductive ink, Feldman can not remedy the deficiencies of Say and Charlton nor provide suggestion or motivation for combining the references.

Applicants thus, respectfully request withdrawal of this rejection.

Claims 32 and 34- Say, Charlton, and Yamashita

Claims 32 and 34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Say in view of Charlton, and in further view of Yamashita.

As stated above, the combination of Say and Charlton fails to render the claimed invention obvious. As Yamashita has merely been cited for its alleged teaching of polyethylene glycol as a hydrophilic polymer, Yamashita fails to remedy the deficiencies of Say and Charlton nor provide suggestion or motivation for combining these references.

Applicants thus, respectfully request withdrawal of this rejection.

Claims 32-34- Feldman, Say, Charlton, and Yamashita

Claims 32-34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Feldman in view of Say and Charlton, and in further view of Yamashita.

As noted above, the combination of Feldman in view of Say and Charlton fails to render the claimed invention obvious. As Yamashita has merely been cited for its alleged teaching of polyethylene glycol as a hydrophilic polymer, Yamashita fails to remedy the deficiencies of Feldman, Say and Charlton nor provide suggestion or motivation for combining these references.

Applicants thus, respectfully request withdrawal of this rejection.

Conclusion

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Office finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, reference number ADCI-073.

Respectfully submitted,
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Date: February 8, 2010

By: /Edward J. Baba, Reg. No. 52,581/
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Enclosure

- Exhibit 1 - Skoog, et al. *Principles of Instrumental Analysis* 4th Edition 1992: pp. 466-475

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